

K121920

ATTACHMENT 2**510(k) SUMMARY****JUN 27 2013**

510(k) Owner: Sunetics International Marketing Group LLC
892 Steger Towne Rd Suite # 44
Rockwall, TX 75032
Contact: John Carullo
Phone: 214-683-0724

Date Summary Prepared: June 21, 2012

Device: **Trade Name:** Sunetics LaserBrush
Common/Classification Name: Laser, Comb, Hair
Product Code OAP
21 C.F.R. § 890.5500 (Infrared lamp)
Classification: Class II

Predicate Device: HairMax LaserCombs - models: Advanced 7, Lux 9, Professional 12
Lexington International, LLC
K110233, K103368, K112524

Device Description: The Sunetics LaserBrush consists of a handheld low-level laser device intended to promote hair growth. Depending upon the Sunetics LaserBrush model, the device provides distributed laser light using seven (7), nine (9), or twelve (12), collimated, 650 nm, <5 mW laser modules, while brush bristles simultaneously part the user's hair to ensure that the laser light reaches the user's scalp.

Intended Use: The Sunetics LaserBrush is indicated to treat Androgenetic Alopecia, promote hair growth and prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV & also in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss & Fitzpatrick Skin Types I to IV.

Technological Characteristics: The Sunetics LaserBrush has the same intended power, wavelength, energy source, laser beam pattern, laser treatment field, consumer usage focal point, energy delivery, power supply, treatment time, indication for use, and target population as the Hairmax LaserComb.

Biocompatibility Data: Not applicable.

Performance Data: The laser wavelength length, average and peak power levels, laser treatment field and energy delivery of the Sunetics LaserBrush and the Lexington Hairmax LaserComb were substantially equivalent.

Conclusions: The performance data discussed above demonstrate that the Sunetics LaserBrush device is as safe and effective as the predicate device.

June 28, 2012



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Sunetics International Marketing Group, LLC
% Mr. John Carullo
892 Steger Towne Road, Suite 44
Rockwall, Texas 75032

June 27, 2013

Re: K121920
Trade/Device Name: Sunetics LaserBrush
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: June 05, 2013
Received: June 11, 2013

Dear Mr. Carullo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Mr. John Carullo

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

Indications for Use

510(k) Number K121920
(if known):

Device Name: Sunetics LaserBrush models: LHB 7, LHB 9, LHB 12

Indications for Use: The Sunetics LaserBrush is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV.

The Sunetics LaserBrush is indicated to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.06.24 17:36:30 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

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June 28, 2012